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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/982,763 | 10/18/2001 | Ruth Elinor Bauhahn | 11738.00039 | 8709 |
| 22908 | 7590 | 06/20/2005 | | |
| BANNER & WITCOFF, LTD. TEN SOUTH WACKER DRIVE SUITE 3000 CHICAGO, IL 60606 | | | EXAMINER BOCKELMAN, MARK | |
| | | | ART UNIT 3762 | PAPER NUMBER |

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,763

Applicant(s)

BAUHAHN ET AL.

Examiner

Mark W. Bockelman

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3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 44 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-24-2005 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 8-9 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi USPN 4,469,481.

Kobayashi teaches a preset program stored in a pump (column 2 lines 16-20, 31-35) which may be modified (column 2 lines 37-41) and includes personalized programs based upon patient activity (column 19 lines 14-16). The personalized program is then executed (column 2 lines 25-35, column 18, line 65 to column 19 line 25 as well as

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column lines 8-23 and 44-46). Various therapy settings including rates, dosages, start and stop times can be found in column 8 lines 52-55, column 9 lines 19-50, and column 16 lines 17-25. The pump may be an external pump (column 7 lines 21-25, column 18 lines 35-51). The personalized program may be stored in the pump (column 16 lines 28-43). A programmer is taught as communicating with the pump at column 16, lines 41-43, 52-58).

Claims 1-2, 6-7, 9, 45 and 46 rejected under 35 U.S.C. 102(b) as being anticipated by Fischell WO 84/03218.

Fischell teaches a preset program stored in a drug delivery pump, its modification and creating a personalized program and executing it at page 3 lines 9-32, page 2 lines 28-29, page 3 line 4 and page 10 line 13- page 11 line 4. A personalized dose setting is taught at page 3, lines 14-20 and page 10 lines 24-26. The pump member may be implantable (page 2 line 28 and pages 10 lines 13-17). The pump may also be external (page 12 lines 14-15) and also may be a telemetry programmed pump (page 10 line 20-29) and page 2 lines 28-29 and page 3 lines 6-12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-5 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fischell WO 84/03218. The description of the patient control on page 3 lines 15-17 and page 33 lines 21- page 34 line 2 seem to suggest that the patient controls the rates as well as start and stop times, which are otherwise considered obvious in view of the teachings of Kobayashi USPN 4,469,481 (see previous 102 rejection under Kobayashi).

Claims 1-9, 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ford et al USPN 5,681,285 in view of Franetzki et al USPN 4,282,872

Ford et al teach the storage of a library of drug delivery programs in a pump. Various drug programs can be called up and parameter settings which includes infusion rates, drug dosages (column 3 lines 12-15), as well as preprogrammed with an Auto Schedule function for start and stop times (column 13 line 65- column 14 line 8). After setting the parameters the new program be saved under a user specified file name for recall and usage. (see entire document- see column 12 lines 41-60 for an example) A programmer, either the front display or a computer, may be used to store new drug programs. While Ford et al does not teach a program parameter based upon patient activity, Franetzki et al is cited as demonstrating basing a program on such a parameter for drug delivery is conventional (column 2 lines 23-31). Franetzki also teaches that such pumps may be external or implantable and program control handled by telemetry if a long term treatment is needed. The modifications would have been obvious at the time of the invention based upon the teachings of Franetzki et al.

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Claims 1-7, 9, 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell USPN 5,456,691 in view of Kobayashi USPN 4,469,481 or vice versa. Snell teach a method of programming and using an implantable device with a telemetric external programmer. Various program modules 30 are stored within the implantable device, which may be called upon by the external programmer 12 to build new programs to be executed by the implanted device. The implantable device is stated to be an implantable pump (see column 7 lines 35-50) which allows the physician to select various modules to create individual specific programs. Applicant differs in reciting that a patient activity parameter that includes a dosage and time of delivery. Kobayashi et al teach that drug delivery programs include such parameters and thus the examiner concludes that such would have been obvious in using the Snell system to implement the changing of the patient settings or to include the patient setting in the Snell programming device.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snell USPN 5,456,691 in view of Kobayashi USPN 4,469,481 as applied to claims 1-7, 9, 45-46 above, and further in view of Franetzki et al et al USPN 4,282,872. To have made provided the pump as an implantable pump or an external pump depending upon the length of time needed would have been readily apparent to one of ordinary skill in the art as evidenced by Franetzki.

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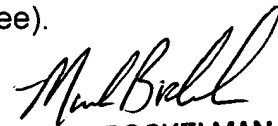
Response to Arguments

Applicant's arguments with respect to claims 1-9, 45-46 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Thursday 10-8:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MARK BOCKELMAN
PRIMARY EXAMINER

MWB

June 12, 2005